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Glaxo Failed to Disclose Avandia Studies, FDA Says (Update5)

By Catherine Larkin and Andrea Gerlin

April 8 (Bloomberg) -- **GlaxoSmithKline Plc**, Europe's largest drugmaker, failed to properly disclose studies of Avandia, the diabetes pill linked to potentially deadly side effects, U.S. regulators said.

The violations ``are serious and may be symptomatic of underlying post-marketing safety reporting failures,'' the Food and Drug Administration said in a **letter** posted today on its Web site. The agency said it was never told about nine studies and an additional 11 weren't included in required annual reports from 2001 to 2007.

Avandia **sales** plunged last year after a May 21 report in the New England Journal of Medicine linked the drug to a 43 percent increased risk of heart attacks, prompting U.S. and European regulators to strengthen warnings on its prescribing information. The FDA found unreported research while inspecting paperwork at London-based Glaxo's offices in Research Triangle Park, North Carolina from August to November, according to the letter.

``The company is not out of the woods on this one,'' said **Jeremy Batstone-Carr**, an equity strategist at Charles Stanley Group Plc in London, in a phone interview today. ``The FDA has become extremely risk-averse and has therefore raised the bar for every company.''

Glaxo dropped 35 pence, or 3.1 percent, to 1,105 pence in London trading. The drugmaker has **fallen** 22 percent in the past 12 months.

Glaxo's Response

Reports of side effects prompted two of the studies, the FDA said. None of the research kept from the FDA raised new concerns about potential safety risks, company spokeswoman **Nancy Pekarek** said today in a phone interview. Glaxo put in place new employee training programs after the FDA inspection to ensure that appropriate data is sent to the agency from now on, she said.

``Of the studies that were actually omitted from the FDA in any type of reporting, those studies did not show safety events,'' Pekarek said. ``The information that the FDA needed was provided to them before'' the agency changed the prescribing information.

The FDA's oversight of drug safety has been criticized by lawmakers and consumer groups who say it shouldn't have taken years to identify side effects from drugs such as Avandia and **Merck & Co.**'s withdrawn painkiller Vioxx. The agency has since toughened its standards for new drugs, approving 19 last year, the fewest since 1983.

Pozen Shares Fall

Pozen Inc., the drug developer working with Glaxo to produce a new migraine medicine called Treximet, fell the most in six months in Nasdaq Stock Market trading on concerns that the warning letter may delay the new drug's approval. The FDA is scheduled to decide on the companies' application by April 15, though it may delay action for three to six months while Glaxo addresses the concerns in the warning letter, one analyst said.

``While the potential impact on Treximet from the FDA's warning letter on GSK's Avandia is unclear, net-net, we view this as discouraging,'' said **Eun Yang**, an analyst who covers Pozen for Jefferies & Co. in New York, in a note to clients today.

Pozen, of Chapel Hill, North Carolina, fell 95 cents, or 8.2 percent, to $10.70 in composite trading at 4 p.m. New York time, its biggest percentage decline since Oct. 10.

Avandia, approved by the FDA in 1999, was the world's best- selling diabetes pill before safety concerns emerged. Worldwide sales dropped 37 percent to 877 million pounds ($1.73 billion) last year.

Online Data

Glaxo began posting information from its studies on the Internet in 2004 after former New York Attorney General **Eliot Spitzer** sued the company for allegedly withholding information from doctors about the dangers of giving the antidepressant Paxil to children. The company's Clinical Trial Register now includes data from most of the studies cited in

the FDA's letter.

Steven Nissen, chairman of cardiology at the Cleveland Clinic Foundation, used Glaxo's online records of 42 studies as the basis for the report in the New England Journal on Avandia's heart risks. Glaxo said after the report was released that its review, submitted to the FDA two years earlier, suggested a 31 percent greater chance of heart complications in patients on Avandia.

``The FDA can only do its job if they have all of the information that is required by law,'' Nissen said today in a phone interview.

All of the studies Nissen used were also available to the FDA, Glaxo's Pekarek said.

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